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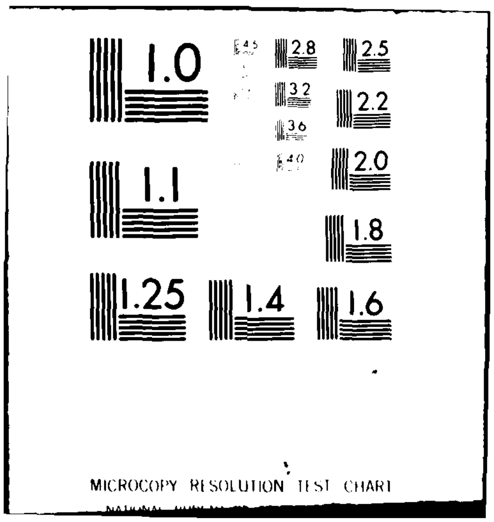
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COMBINED STANDBY TRANSVENOUS DEFIBRILLATOR AND
DEMAND PACEMAKER

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FINAL REPORT

Leo Rubin, M.D.

December 1975

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The major objective of this effort was to find the minimum energy required for reliable defibrillation. In working toward this objective six catheter types were designed and evaluated; the effects of two closely spaced (in time) defibrillation pulses applied to one and two adjacent sites within the ventricle was experimentally examined; the effects of polarity of both unipolar and bipolar defibrillation pulses were evaluated; a comparison of the energy requirements for intracardiac and epicardial defibrillation was performed; and the pacing thresholds of the relatively large area defibrillation →
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catheters was determined.

The lowest defibrillation energies observed (1.3 Joules) were obtained with a single pulse applied to the epicardial surface. There was no difference in the energy required for defibrillation due to pulse polarity. However, bipolar defibrillation requires about 50% less energy than unipolar defibrillation. Double pulses required more energy than single pulses in all cases evaluated. Defibrillation threshold energies are relatively independent of electrode area as long as the area is greater than a critical minimum. Pacing thresholds are one to two orders of magnitude greater with large area defibrillation electrodes than with conventional pacing electrodes.

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INTRODUCTION AND SUMMARY

This final report presents the results of a 12 month effort under Contract Number DAMD 17-74-C-4108 - "A Combined Transvenous Defibrillator and Demand Pacemaker for Army Patient Field Support" -, to evaluate and establish ceriteria for reliable, safe, transvenous defibrillation of the heart.

The major objective of this effort was to find the minimum energy required for reliable defibrillation. In working toward this objective six catheter types were designed and evaluated; the effects of two closely spaced (in time) defibrillation pulses applied to one and two adjacent sites within the ventricle was experimentally examined; the effects of polarity of both unipolar and bipolar defibrillation pulses were evaluated; a comparison of the energy requirements for intracardiac and epicardial defibrillation was performed; and the pacing thresholds of the relatively large area defibrillation catheters was determined.

The lowest defibrillation energies observed (1.3 Joules) were obtained with a single pulse applied to the epicardial surface. There was no difference in the energy required for defibrillation due to pulse polarity. However, bipolar defibrillation requires about 50% less energy than unipolar defibrillation. Double pulses required more energy than single pulses in all cases evaluated. Defibrillation threshold energies are relatively independent of electrode area as long as the area is greater than a critical minimum. Pacing thresholds are one to two orders of magnitude greater with large area defibrillation electrodes than with conventional pacing electrodes.

Due to the very large number of variables investigated during this effort it was impossible to thoroughly evaluate all of the possible parameters. However, several areas such as double pulse and very small area defibrillation electrode designs can be eliminated for consideration in further work and other areas such as determining an optimum electrode spacing warrant additional effort.

PROCEDURE

Dogs weighing from 9 to 28 kilograms were anesthesized with sodium pentobarbital injected intravenously with a dose of 20 mg/kg. In the intracardiac experiments an external jugular vein cutdown was performed, the vein cannulated and the catheter inserted under fluoroscopic control. The position of the catheter was then confirmed both by attaching the distal electrode to an EKG V lead and noting S-T segment elevation and by obtaining pacing thresholds. Fibrillation was induced by the application of 2 to 4 seconds of 60 hertz current via the catheter.

UNIPOLAR VS. BIPOLAR DEFIBRILLATION

Figure 1 is a scale drawing of a typical bipolar catheter used in this study. Bipolar defibrillation pulses are applied directly to the two available leads. One lead is connected to all of the distal electrodes (3 in the illustration shown in figure 1) and the other lead is connected to all of the proximal electrodes. For unipolar defibrillation the pulses are applied between the lead connected to the set of distal electrodes and a 25 square cm. stainless steel paddle placed either on the chest or the top. Table 1 is a summary of the average energy, per unit weight, required for first trial successful defibrillation using catheters with distal electrode areas of 1.2 square cm. The data in table 1 was obtained from 16 episodes of unipolar defibrillation and 26 episodes of bipolar defibrillation on dogs ranging from 11.4 k grams to 19 k grams. An unexpected result of the data is the fact that unipolar defibrillation which has 55% lower resistance also has a 50% higher defibrillation threshold than bipolar defibrillation even though one of the electrodes in both techniques is in the apex of the right ventricle. This data indicates that a substantial portion of the delivered energy in unipolar defibrillation is dissipated in low impedance blood and tissue outside the heart.

DEFIBRILLATION THRESHOLD ENERGY VS. ELECTRODE AREA

The objective of this set of experiments was to determine the effect of distal electrode area on defibrillation threshold energy. Figures 2 and 3 are photographs of two of the catheters used in these experiments. The catheter shown in Figure 2 is a unipolar catheter with a sliding sleeve which permits the exposure of one to four electrodes each of which has an electrode area of approximately 0.6sq. cm. The bipolar catheter shown in Figure 3 has independent connections to each of the three 0.3 sq. cm. distal electrodes.

The results of these experiments are summarized in Tables 2 and 3 which give the average defibrillation energy thresholds per kilogram of body weight as a funtion of electrode area. Tables 2 and 3 show that bipolar defibrillation thresholds are less than unipolar for all of the electrode areas considered. The difference in resistance and energy for the 1.2 sq. cm. unipolar electrodes shown in Tables 1 and 2 is due to the location of the paddle required for unipolar defibrillation. That is the data in Table 1 was obtained from defibrillation episodes where the paddle was located on the chest and all of the data in Table 2 was obtained from defibrillation episodes where the paddle was located on the hip.

The data in Tables 2 and 3 tend to indicate that small area electrodes yield small defibrillation threshold energies. However, all of the small area data was obtained from dogs weighing less than 10 kg. Defibrillation attempts on larger dogs with small area catheters were unreliable and in many cases completely unsuccessful due to electrode polarization.

An example of electrode polarization is shown in the scale tracing of Figure 4a. The top and bottom tracings in Figure 4a shows defibrillation voltage and current wave forms obtained while attempting bipolar defibrillation of an 11.4 kg. dog using 0.6 sq. cm. electrodes. For reference, unpolarized tracings obtained during the same experiment using a slightly lower available energy level are shown in Figure 4b. Figure 4b shows that of the 27 Joules available, 19.1 were delivered in the 10 m sec pulse. In comparison, Figure 4a shows that of the 31 Joules available only 14.6 were actually delivered due to polarization of the electrode.

DOUBLE PULSE DEFIBRILLATION

Kugelberg suggested that at the moment when a defibrillation current is applied some of the fibrillating cells are excitable and will be depolarized. Other cells will be refractory and will continue to fibrillate. Hence, in order to obtain total defibrillation both cell groups need to be defibrillated separately. Kugelberg suggested that defibrillation should consist of two pulses with a pulse interval adjusted so that those cells excitable at the moment of the first pulse will be defibrillated and then be refractory during the second pulse. The second pulse should be applied so that it will defibrillate those cells which were refractory to the first pulse and which are now excitable and consequently depolarized.

Based on the above hypothesis apparatus and experiments were designed to compare the defibrillation energy thresholds of single and double pulse defibrillation waveforms. However, in 5 attempts on dogs ranging from in weight 6.8 kg. to 36.4 kg. we were unable to successfully defibrillate transvenously using double pulse waveforms. In all attempts the maximum available energy (of 50 Joules) was used. Successful double pulse defibrillation was achieved when the catheter was sutured to the epicardial surface. In these cases the defibrillation threshold energies were greater than the energy using a single pulse.

HISTOLOGICAL EXAMINATION

Transthoracic electrical current can damage the myocardian when the energy delivered exceeds one ampere/kilogram body weight in experimental animals.[1] Theoretically the more proximate the electrodes are to the heart and the smaller the area of contact, the higher is the electrical density in tissue adjacent to the electrodes and one would assume, the greater is the predisposition to myocardial injury.

In 1954 Tedeschi and White,[2] described necrosis of the epicardium and myocardium following alternating current and condenser discharge countershocks in dogs. In these experiments the electrodes were placed directly on the heart and the lesions were most prominent at the siteof electrode application. The early lesions showed focal hyperemia and hemorrhage, cell necrosis, and polymophonuclear infiltration. The tissue procured 15 days following countershock showed progressive replacement of necrotic tissues by fibrous scar. In 1964 Anderson et al[3] noted that the severity of the myocardial damage was related quantitatively to the electrical energy delivered. The greatest damage occurred beneath the arms of the leectrodes. The lesions ranged from minor sized focal ones to transmural necrosis and subsequent fibrous scar.

Tacker, Geddes et al[4] have demonstrated the energy dose needed is directly proportional to the size of the animal to be defibrillated. Davis et al[1] found myocardial damage ranged from minimal to none in those animals receiving less than twice the threshold and foci of trans-culated threshold value. The most extensive myocardial damage occurred in animals receiving the largest overdose.

Six mongrel dogs ranging from 20-45 lbs. after undergoing 4-22 episodes each of fibrillation and defibrillation using threshold or slightly higher energy doses for defibrillation were examined. They were examined for gross anatomical pathological lesions and were subsequently fixed in 10% formalin for 24-48 hours for histological examination. Photomicrographs of sections of the right ventricle obtained from the site of electrode contact with the endocardiam show no hemorrhage, petechiae, thermal injury or foci of necrosis.

A total of 6-10 tissue blocks from each heart were processed for histologic examination using hemotoxylin and eosin.

The endocardium was intact. They were devoid of inflammatory cells. The individual muscle fiber showed no loss of definition or cross striation. There were no histological features of "myofibrillar degenerations."

EPICARDIAL DEFIBRILLATION

It has been stated that the maintenance of spontaneous ventricular fibrillation depends on a certain amount of excitable myocardium, the critical mass, then reducing the excitable ventricular mass to a value less than this critical mass should cause defibrillation to terminate. While transvenous defibrillation does not require a thoracotomy, its effectiveness is dependent on precise placement and maintenance of a catheter at an optimal site. This concept of critical mass depolarization leads us to postulate that the energy requirements would be significantly lowered if the catheter electrodes would be in or on the ventricle rather than intracavitary in the right ventricle.

For epicardial defibrillation experiments a thoracotomy was first performed. Then either the catheter shown in Figure 2 was sutured directly to the epicardial surface of the left ventricle or specially designed epicardial catheters were appended to the epicardial surface. Two types of epicardial catheters were evaluated. These are shown in Figures 5 and 6. The catheter in Figure 5 is a disk electrode with two "barbs" which permits direct attachment to the epicardial surface. The catheter shown in Figure 6 is a "twist on" disk electrode also developed for direct attachment to the epicardial surface.

There were a total of 125 episodes of fibrillation on 13 dogs ranging in weight from 10 kg to 17.2 kg. The defibrillation threshold energies of positive and negative pulses were equal and there was no significant difference whether one, two, three, or four electrodes were appended to the epicardial surface. The defibrillation threshold energy using the catheter of Figure 2 was a remarkably low 0.24 Joules per kilogram of body weight. The threshold energies of the "special" epicardial catheters were both a disappointingly high 1.8 Joules per kilogram.

PACING IMMEDIATELY AFTER DEFIBRILLATION

Initial pacing thresholds using the convential defibrillation electrodes shown in Figure 1 are typically in the 1 to 3 MA range.

However, immediately after the application of high energy defibrillation pulses pacing thresholds have been observed to rise to greater than 20 MA for the first few minutes and takes as long as 30 minutes to return to normal. In order to reduce the post-defibrillation thresholds a new catheter was designed and fabricated.

The new catheter has the same electrode size and spacings as the catheter shown in Figure 1 with the exception of the most distal or "tip" electrode. The button tip electrode has a very small 0.2 sq. mm surface area, separate electrical contact, and is used only for pacing. The current required for pre-fibrillation pacing using the button tip has been less than 0.5 MA in every case and is often less than 0.1 MA. The photographs in Figure 7 are of continuous EKG strips obtained during and immediately after fibrillation episodes. Both Figures 7a and 7b show fibrillation with successful tranvenous defibrillation. Figure 7a shows A-V dissociation and a ventricular response of 33 beats per minute after the defibrillation shock. In this figure pacing at 20 MA was unsuccessful using a conventional defibrillation electrode. Figure 7b shows defibrillation followed by a brief run of ventricular tachycardia and subsequent A-V dissociation. However, in this case pacing using the button tip electrode was successful at 0.5 MA. Defibrillation thresholds using the catheter with the botton tip pacing electrode are the same as conventional catheters with equivalent area defibrillation electrodes. In every case the current required for pacing capture immediately after defibrillation has been less than 2 MA and as low as 0.1 MA.

The incorporation of separate defibrillation and pacing electrodes is essential for catheters which are designed for combined defibrilla- and pacing.

FUTURE WORK

The reliability of transvenous defibrillation can only be demonstrated by extensive animal trial and by bench testing. Electrical discharges, even when delivered transthoracically, occasionally can damage the heart. The more poximate electrodes are to the heart, and the smaller the contract area can produce a higher current density in the tissue adjacent to the heart. It would therefore seem fair to draw a conclusion that the incidence of myocardial damage would be much greater by transvenous defibrillation than external defibrillation. However, preliminary lab experiments have not substantiated this hypothesis. In experiments where animals have been defibrillated more than twenty (20) times - histologic examination of the heart preparation have not revealed any areas of electrical burning, coagulation necrosis or petechial hemorrhages.

A substantial effort should be dedicated in demonstrating that transvenous defibrillation does not carry a statistically higher morbidity and mortality than convential transthoracic defibrillators. This will require a large number of animal tests and extensive pathological examination using both optical and scanning electron microsopic examinations of tissue.

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	Weight (kilograms)	Energy (Joules)	Energy per kilogram	Resistance (ohms)
Bipolar	16.5	26.3	1.6	136
Unipolar	11.4	31.8	2.8	75

TABLE 1. AVERAGE UNIPOLAR AND BIPOLAR DEFIBRILLATION THRESHOLD ENERGIES WITH 1.2 SQ. CM. ELECTRODES.

Electrode Area (sq. cm)	0.6	1.2	1.8	2.3
Threshold Energy (Joules/kg)	2.1	2.2	2.2	2.4
Resistance (ohms)	237	181	151	140

TABLE 2. UNIPOLAR DEFIBRILLATION THRESHOLD ENERGY VERSES ELECTRODE AREA.

Electrode Area	0.3	0.6	0.9	1.2
Threshold Energy	1.1	1.4	1.3	1.6
Resistance	240	160	143	136

TABLE 3. BIPOLAR DEFIBRILLATION THRESHOLD ENERGY VERSES ELECTRODE AREA

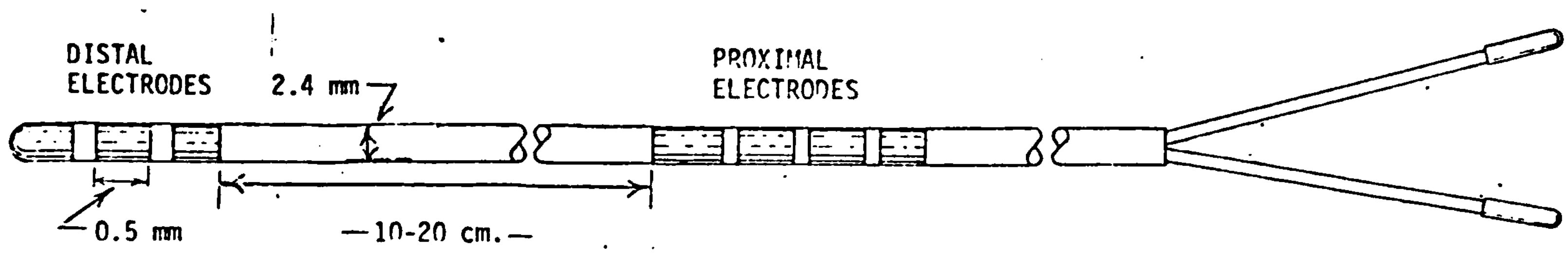


Fig. 1 Typical Defibrillation Catheter

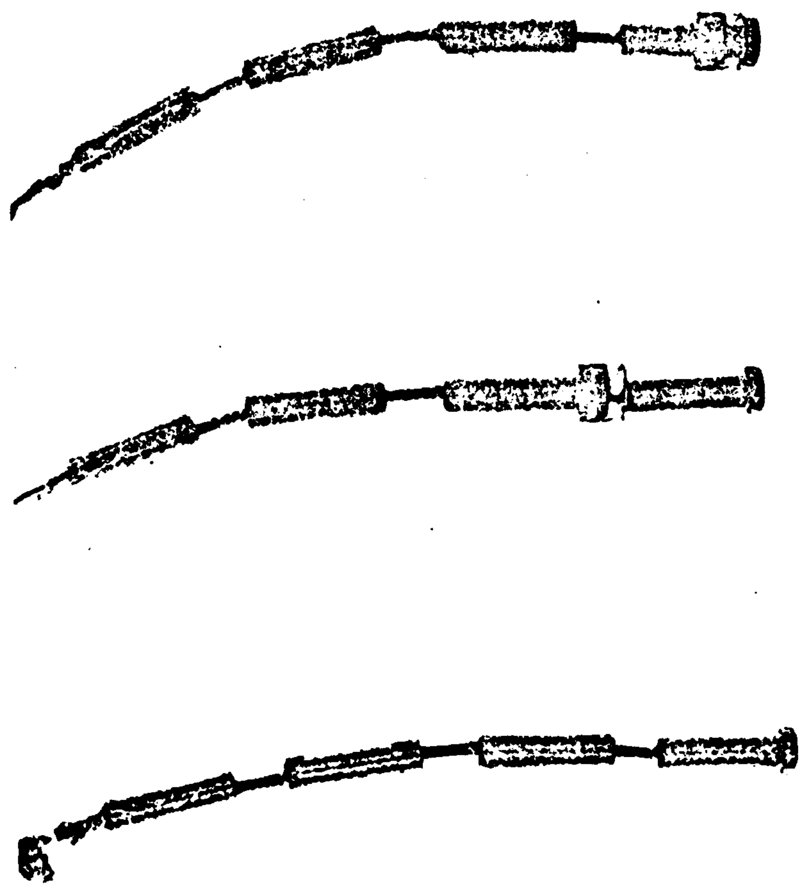


Figure 2. Sliding sleeve unipolar catheter

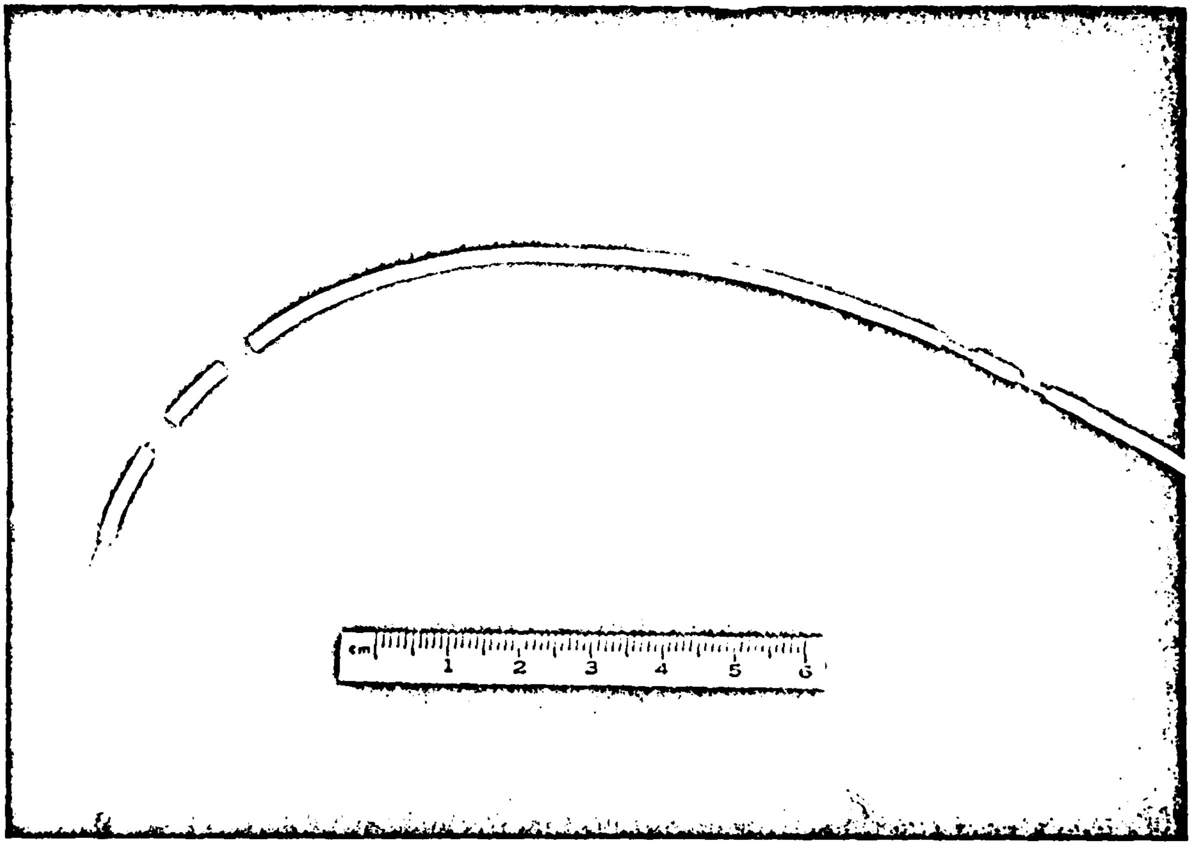
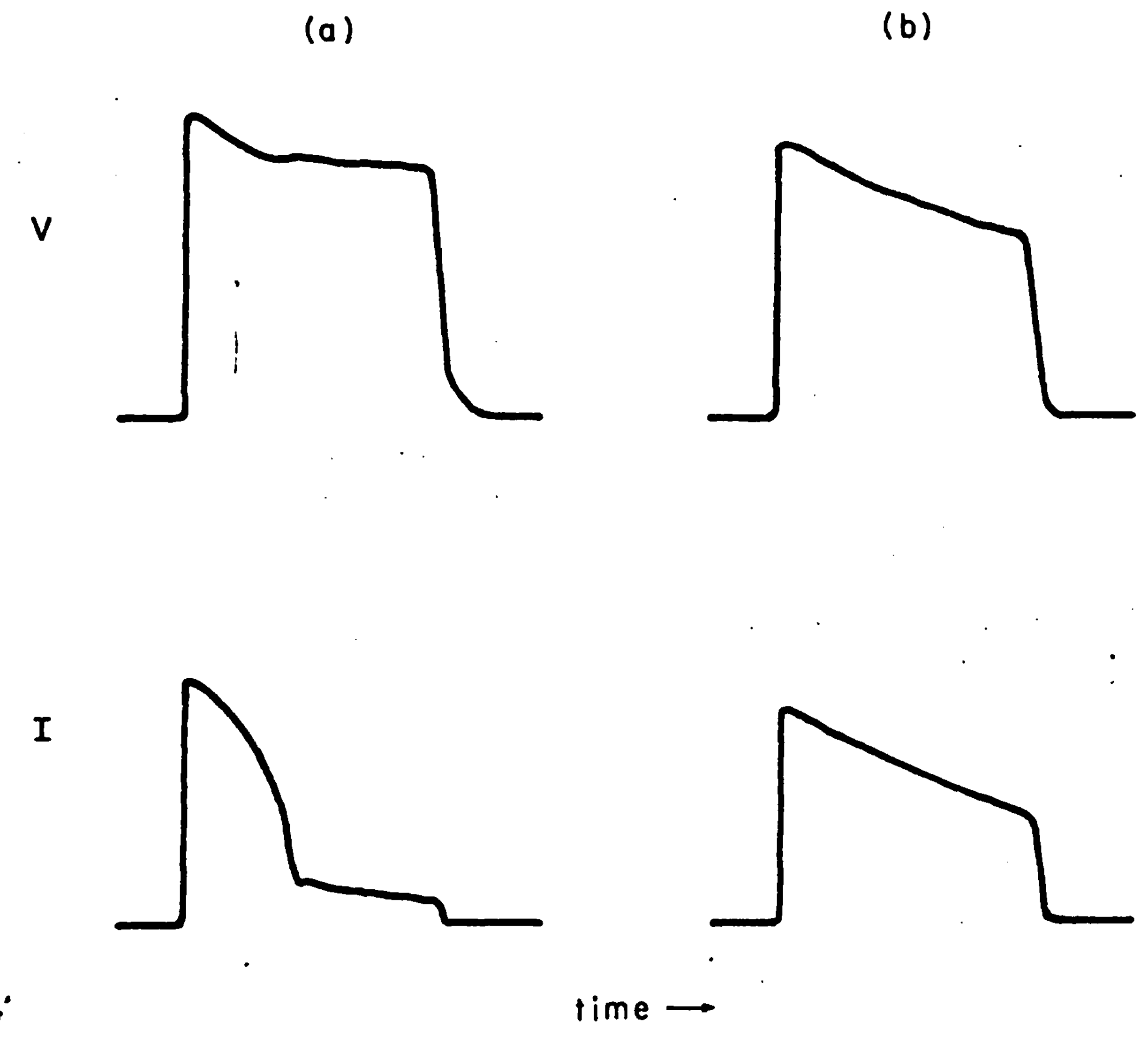


Figure 3. Selectable distal area bipolar catheter

FIG. 4 DEFIBRILLATION VOLTAGE AND CURRENT WAVEFORMS
(a) WITH POLARIZATION AND (b) WITHOUT POLARIZATION



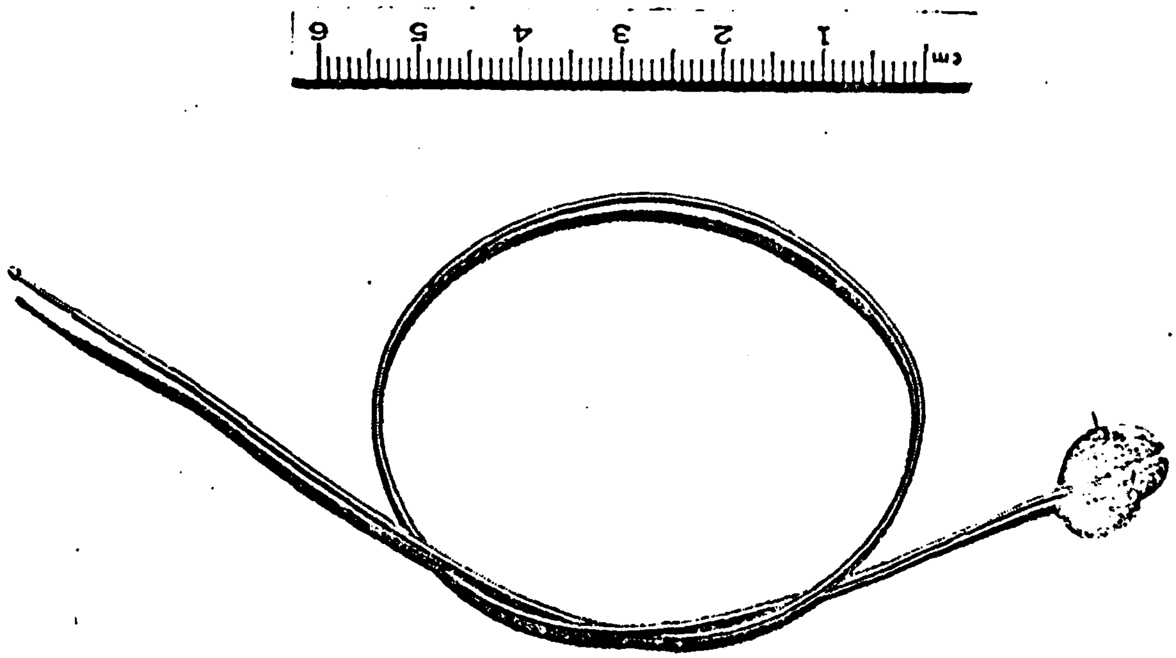


Figure 5. Epicardial disk electrode catheter

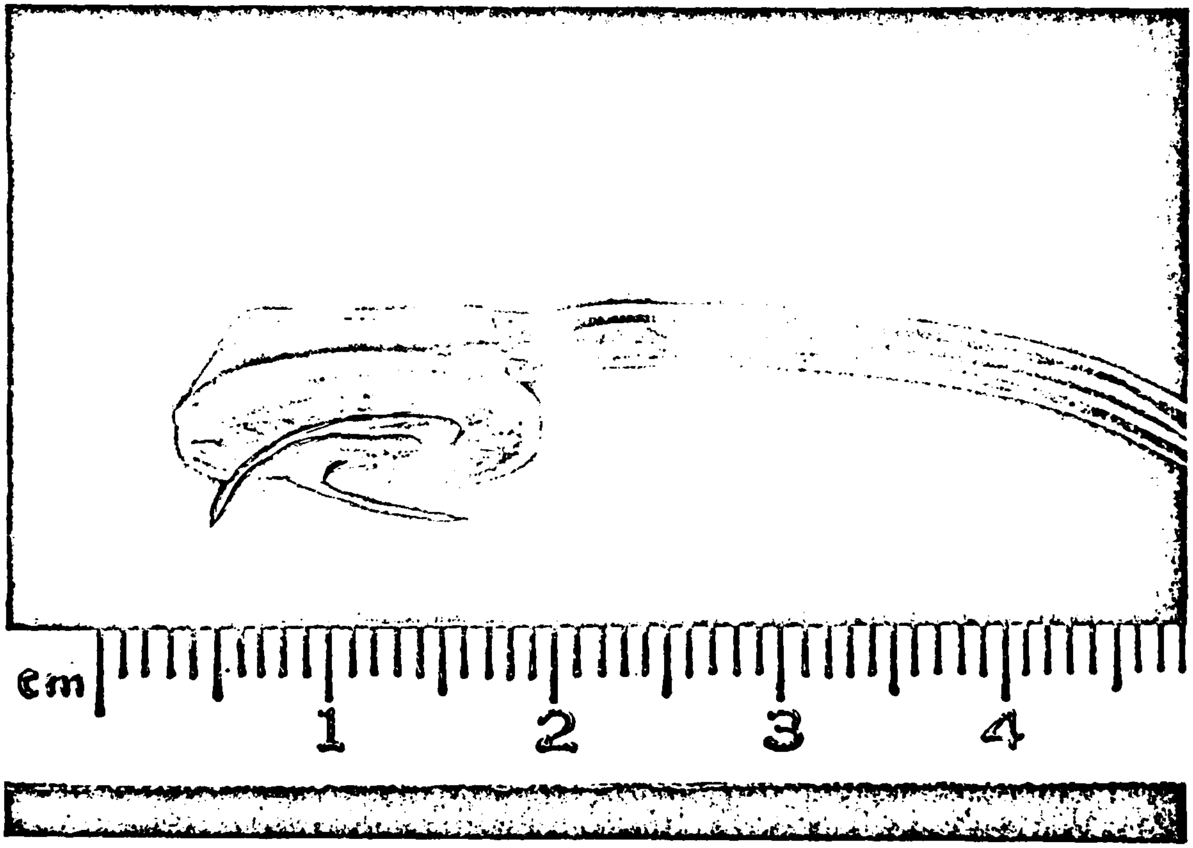


Figure 6. Epicardial "twist on" electrode

a.

b.

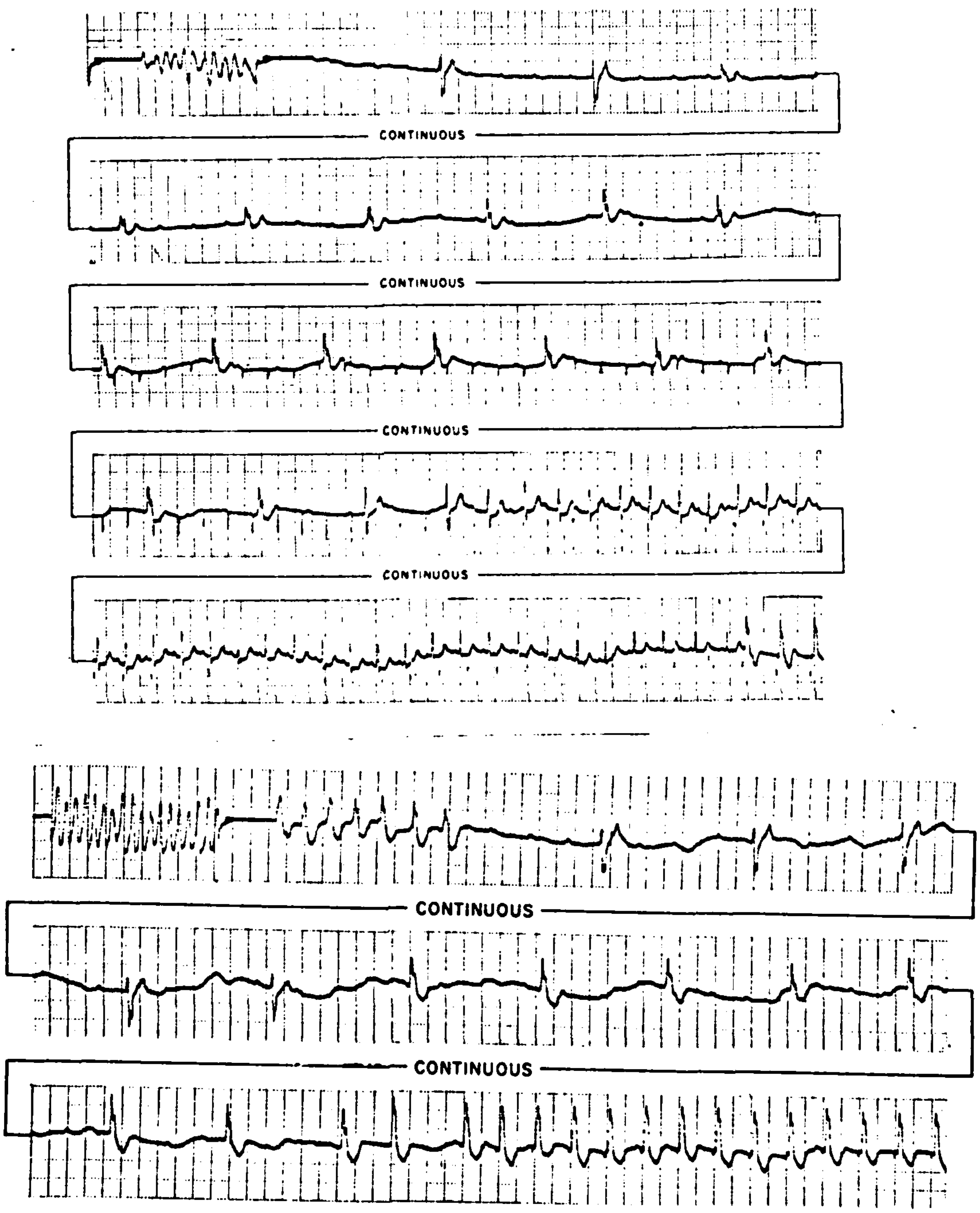


Figure 7. EKG's obtained during and immediately after fibrillation.
a. Failure to pace with 20 ma
b. Pacing capture with 0.5 ma

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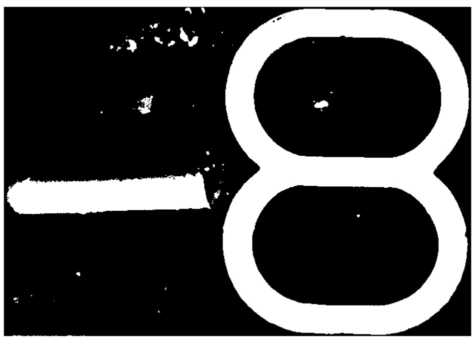
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